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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,793	03/22/2004	Teit E. Johansen	19313-001CON	2372

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EXAMINER

BALLARD, KIMBERLY A

ART UNIT PAPER NUMBER

1649

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,793

Applicant(s)

JOHANSEN ET AL.

Examiner

Kimberly A. Ballard

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 66-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 2, classified for example in class 514, subclass 2.
- II. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 4, classified for example in class 514, subclass 2.
- III. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 5, classified for example in class 514, subclass 2.
- IV. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 6, classified for example in class 514, subclass 2.
- V. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 7, classified for example in class 514, subclass 2.
- VI. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 9, classified for example in class 514, subclass 2.

- VII. Claims 66-72, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 10, classified for example in class 514, subclass 2.
- VIII. Claims 66-72, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 11, classified for example in class 514, subclass 2.
- IX. Claims 66-72, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 12, classified for example in class 514, subclass 2.
- X. Claims 66-71, drawn to a method of treating or preventing a disorder of the eye, comprising administering a Neublastin polypeptide of SEQ ID NO: 16, classified for example in class 514, subclass 2.
- XI. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 2, classified for example in class 514, subclass 2.
- XII. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 4, classified for example in class 424, subclass 93.2.
- XIII. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a

polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 5,
classified for example in class 424, subclass 93.2.

- XIV. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 6, classified for example in class 424, subclass 93.2.
- XV. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 7, classified for example in class 424, subclass 93.2.
- XVI. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 9, classified for example in class 424, subclass 93.2.
- XVII. Claims 73-79, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 10, classified for example in class 424, subclass 93.2.
- XVIII. Claims 73-79, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 11, classified for example in class 424, subclass 93.2.

- XIX. Claims 73-79, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 12, classified for example in class 424, subclass 93.2.
- XX. Claims 73-78, drawn to a method of treating or preventing a disorder of the eye, comprising administering a virus vector comprising a polynucleotide encoding a Neublastin polypeptide of SEQ ID NO: 16, classified for example in class 424, subclass 93.2.
- XXI. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 2, classified for example in class 424, subclass 93.7.
- XXII. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 4, classified for example in class 424, subclass 93.7.
- XXIII. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 5, classified for example in class 424, subclass 93.7.
- XXIV. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin

polypeptide of SEQ ID NO: 6, classified for example in class 424, subclass 93.7.

XXV. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 7, classified for example in class 424, subclass 93.7.

XXVI. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 9, classified for example in class 424, subclass 93.7.

XXVII. Claims 80-86, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 10, classified for example in class 424, subclass 93.7.

XXVIII. Claims 80-86, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 11, classified for example in class 424, subclass 93.7.

XXIX. Claims 80-86, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 12, classified for example in class 424, subclass 93.7.

XXX. Claims 80-85, drawn to a method of treating or preventing a disorder of the eye, comprising administering a cell line expressing a Neublastin polypeptide of SEQ ID NO: 16, classified for example in class 424, subclass 93.7.

The inventions are distinct, each from the other because of the following reasons:

The methods of using the polypeptides of Inventions I-X are distinct, each from the other, because the different methods employ the use of distinct polypeptides, the polypeptides have different amino acid sequences and different expression patterns, and thus are regulated differently, and each sequence requires a separate search and consideration of the appropriate databases and non-patent literature. Thus the search for each method is not co-extensive. Methods requiring viral vectors comprising polynucleotides encoding said polypeptides (Inventions XI-XX) and methods requiring cells expressing said polypeptides (Inventions XXI-XXX) are thus also distinct.

Inventions (I-X) and each of (XI-XX) and (XXI-XXX) are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to methods that are distinct from each other with regard to administered agents, and are not required one for the other. For example, the methods of inventions I-X employ the administration of polypeptides, whereas the methods of inventions XI-XX involve the

administration of viral vectors comprising polynucleotides and the methods of inventions XXI-XXX involve administering cell lines expressing a particular polypeptide, wherein none of the methods recite the use of any other method. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.
November 13, 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER